Senate

General Assembly

File No. 234

February Session, 2000

Substitute Senate Bill No. 371

Senate, March 27, 2000

The Committee on General Law reported through SEN. COLAPIETRO of the 31st Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

An Act Concerning The Classification And Regulation Of Drugs By The Department Of Consumer Protection And The Issuance Of A Temporary Permit To Practice Pharmacy.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Subdivision (49) of section 21a-240 of the general statutes is repealed and the following is substituted in lieu thereof:

(49) "Restricted drugs or substances" are the following substances without limitation and for all purposes: Datura stramonium; hyoscyamus niger; atropa belladonna, or the alkaloids atropine; hyoscyamine; belladonnine; apatropine; or any mixture of these alkaloids such as daturine, or the synthetic homatropine or any salts of these alkaloids, except that any drug or preparation containing any of the above-mentioned substances which is permitted by federal food and drug laws to be sold or dispensed without a prescription or written order shall not be a controlled substance; amyl nitrite; the following volatile substances to the extent that said chemical

substances or compounds containing said chemical substances are sold, prescribed, dispensed, compounded, possessed or controlled or delivered or administered to another person with the purpose that said chemical substances shall be breathed, inhaled, sniffed or drunk to induce a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system: Acetone; benzene; butyl alcohol; butyl nitrate and its salts, isomers, esters, ethers or their salts; cyclohexanone; dichlorodifluoromethane; ether; ethyl acetate; formaldehyde; hexane; isopropanol; methanol; methyl cellosolve acetate; methyl ethyl ketone; methyl isobutyl ketone; nitrous oxide; pentochlorophenol; toluene; toluol; trichloroethane; trichloroethylene; 1,4 butanediol.

Sec. 2. Subsection (k) of section 21a-106 of the general statutes is repealed and the following is substituted in lieu thereof:

(k) If it is a **[**drug sold at retail for use by man and contains any quantity of amidopyrine, barbituric acid, cinchophen, bishydroxycoumarin, dinitrophenol, methylparafynol, thiouracil or thyroid, or any derivative of any of these substances, or (1) is a habit-forming drug to which subsection (d) of this section applies; or (2) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (3) is limited by an effective application under section 21a-111 to use under the professional supervision of a practitioner licensed by law to administer such drug, unless it is sold on a written, oral or electronically-transmitted prescription of a practitioner licensed by law to administer such drug; and its label bears the name and place of business of the seller, the serial number and date of such prescription and the name of such practitioner**]** legend drug, as defined in subdivision (14) of section 20-571, as amended by this act, that is not administered, dispensed, prescribed or otherwise possessed or distributed in accordance with

federal and state laws and regulations.

Sec. 3. Section 20-617 of the general statutes, as amended by public act 99-49 and section 38 of public act 99-175, is repealed and the following is substituted in lieu thereof:

Each pharmacist shall include on the label of each prescription container: (1) The quantity of prescribed drug placed in such container, in addition to any other information required by law; and (2) a prominently printed expiration date based on the manufacturer's recommended conditions of use and storage that can be read and understood by the ordinary individual. [under customary conditions of purchase, use and storage based on the manufacturer's recommended guidelines. In the absence of data to the contrary, the] The expiration date required pursuant to subdivision (2) of this section shall be no later than the expiration date determined by the manufacturer.

Sec. 4. Subsection (l) of section 21a-249 of the general statutes is repealed and the following is substituted in lieu thereof:

(l) Any pharmacy may transfer prescriptions for controlled substances included in schedules III, IV and V to any other pharmacy in accordance with the requirements set forth in [21 CFR 1306.26] the federal Controlled Substances Act 21 USC 801 et seq. and the regulations promulgated thereunder, as from time to time amended.

Sec. 5. Subdivisions (13) and (14) of section 20-571 of the general statutes, as amended by section 6 of public act 99-175, are repealed and the following is substituted in lieu thereof:

(13) "Legend device" means a device that is required by applicable federal or state law to be dispensed pursuant only to a prescription or is restricted to use by prescribing practitioners only or that, under federal law, is required to bear either of the following legends: (A)

[**"RX ONLY IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT."**] "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.";

(14) "Legend drug" means a drug that is required by any applicable federal or state law to be dispensed pursuant only to a prescription or is restricted to use by prescribing practitioners only, or means a drug that, under federal law, is required to bear either of the following legends: (A) [**"RX ONLY IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT."**] "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DRUG FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.".

Sec. 6. Section 21a-318 of the general statutes, as amended by section 50 of public act 99-175, is repealed and the following is substituted in lieu thereof:

An application for registration pursuant to this chapter shall be made upon a form provided by the Commissioner of Consumer Protection and shall be accompanied by a fee of [**twenty-five**] ten dollars for [**biennial licensure**] annual registration, except that a practitioner who obtains such registration pursuant to the practitioner's employment with a municipality, this state or the federal government shall not be required to pay the fee.

Sec. 7. Section 20-579 of the general statutes, as amended by section 14 of public act 99-175, is repealed and the following is substituted in lieu thereof:

(a) The commission may refuse to authorize the issuance of a temporary permit to practice pharmacy, may refuse to authorize the issuance or renewal of a license to practice pharmacy, a license to operate a pharmacy or a registration of a pharmacy intern or pharmacy technician, and may revoke or suspend a license or temporary permit to practice pharmacy, a license to operate a pharmacy, or a registration of a pharmacy intern or a pharmacy technician, and may assess a civil penalty of up to one thousand dollars or take other action permitted in subdivision (7) of section 21a-7 if the applicant or holder of the license, temporary permit or registration: (1) Has violated a statute or regulation relating to drugs, devices or the practice of pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (2) has been convicted of violating any criminal statute relating to drugs, devices or the practice of pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (3) has been disciplined by, or is the subject of pending disciplinary action or an unresolved complaint before, the duly authorized pharmacy disciplinary agency of any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (4) has been refused a license or registration or renewal of a license or registration by any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction based on grounds that are similar to grounds on which Connecticut could refuse to issue or renew such a license or registration; (5) has illegally possessed, diverted, sold or dispensed drugs or devices; (6) abuses or excessively uses drugs, including alcohol; (7) has made false,

misleading or deceptive representations to the public or the commission; (8) has maintained exclusive telephone lines to, has maintained exclusive electronic communication with, or has exclusive access to computers located in offices of prescribing practitioners, nursing homes, clinics, hospitals or other health care facilities; (9) has substituted drugs or devices except as permitted in section 20-619, as amended by section 39 of public act 99-175; (10) has accepted, for return to regular stock, any drug already dispensed in good faith or delivered from a pharmacy, and exposed to possible and uncontrolled contamination or substitution; (11) has split fees for professional services, including a discount or rebate, with a prescribing practitioner or an administrator or owner of a nursing home, hospital or other health care facility; (12) has entered into an agreement with a prescribing practitioner or an administrator or owner of a nursing home, hospital or other health care facility for the compounding or dispensing of secret formula or coded prescriptions; (13) has performed or been a party to a fraudulent or deceitful practice or transaction; (14) has presented to the commission a diploma, license or certificate illegally or fraudulently obtained, or obtained from a college or school of pharmacy not approved by the commission; (15) has performed incompetent or negligent work; (16) has falsified a continuing education document submitted to the commission or department or a certificate retained in accordance with the provisions of subsection (d) of section 20-600, as amended by section 29 of public act 99-175; (17) has permitted a person not licensed to practice pharmacy in this state to practice pharmacy in violation of section 20-605, as amended by section 31 of public act 99-175, to use a pharmacist license or pharmacy display document in violation of section 20-608, as amended by section 34 of public act 99-175, or to use words, displays or symbols in violation of section 20-609; or (18) has failed to maintain the entire pharmacy premises, its components and contents in a clean, orderly and sanitary condition.

(b) The commission may refuse to authorize the issuance of a

temporary permit to practice pharmacy, may refuse to authorize the issuance or renewal of a license to practice pharmacy, a license to operate a pharmacy or a registration of a pharmacy intern or pharmacy technician, and may revoke or suspend a license or temporary permit to practice pharmacy, a license to operate a pharmacy, or a registration of a pharmacy intern or a pharmacy technician, or take other action permitted in subdivision (7) of section 21a-7 if the commission determines that the applicant or holder of the license, temporary permit or registration has a condition including, but not limited to, physical illness or loss of skill or deterioration due to the aging process, emotional disorder or mental illness, abuse or excessive use of drugs or alcohol that would interfere with the practice of pharmacy, operation of a pharmacy or activities as a pharmacy intern or pharmacy technician, provided the commission may not, in taking action against a license, temporary permit or registration holder on the basis of such a condition, violate the provisions of section 46a-73 or 42 USC Section 12132 of the federal Americans with Disabilities Act.

Sec. 8. Section 20-590 of the general statutes is amended by adding subsections (c) and (d) as follows:

(NEW) (c) The Department of Consumer Protection shall, upon authorization of the commission, issue a temporary permit to practice pharmacy to an individual who: (1) Practices under the direct supervision of a licensed pharmacist; (2) has an application for reciprocity on file with the commission; (3) is a licensed pharmacist in good standing in a state or jurisdiction from which such state's pharmacy board or commission of pharmacy grants similar reciprocal privileges to pharmacists licensed in this state; and (4) has no actions pending against such individual's license with any state's pharmacy board or commission of pharmacy.

(NEW) (d) A temporary permit to practice pharmacy shall expire at the time the individual with the temporary permit is licensed as a

pharmacist in this state, or not later than six months from the date of issuance of such temporary permit. The Department of Consumer Protection shall not issue more than one temporary permit to practice pharmacy to an individual.

Sec. 9. Section 20-601 of the general statutes, as amended by section 30 of public act 99-175, is repealed and the following is substituted in lieu thereof:

The department shall collect the following nonrefundable fees:

(1) The fee for issuance of a pharmacist license **[**shall be**]** is one hundred dollars, payable at the date of application for the license.

(2) The fee for applying to take the pharmacist license examination required in section 20-590, as amended by section 18 of public act 99-175, and as amended by this act, and in section 20-591, as amended by section 19 of public act 99-175, **[**shall be**]** is one hundred fifty dollars, payable at the date of application for the pharmacist license.

(3) The fee for renewal of a pharmacist license **[**shall be**]** is the professional services fee for class A, as defined in section 33-182l. Before the commission grants a license to an applicant who has not held a license authorized by the commission within five years of the date of application, the applicant shall pay the fees required in subdivisions (1) and (2) of this section.

(4) The fee for issuance of a pharmacy license **[**shall be**]** is six hundred dollars.

(5) The fee for renewal of a pharmacy license **[**shall be**]** is one hundred fifty dollars.

(6) The late fee for an application for renewal of a license to practice pharmacy, a pharmacy license or a permit to sell nonlegend drugs **[**shall be**]** is the amount set forth in section 21a-4, as amended by

section 4 of public act 99-194.

(7) The fee for notice of a change in officers or directors of a corporation holding a pharmacy license [shall be] is thirty dollars for each pharmacy license held. A late fee for failing to give such notice within ten days of the change [shall be] is twenty-five dollars in addition to the fee for notice.

(8) The fee for filing notice of a change in name, ownership or management of a pharmacy [shall be] is forty-five dollars. A late fee for failing to give such notice within ten days of the change [shall be] is twenty-five dollars in addition to the fee for notice.

(9) The fee for application for registration as a pharmacy intern [shall be] is thirty dollars.

(10) The fee for application for a permit to sell nonlegend drugs [shall be] is seventy dollars.

(11) The fee for renewal of a permit to sell nonlegend drugs [shall be] is fifty dollars.

(12) The late fee for failing to notify the commission of a change of ownership, name or location of the premises of a permit to sell nonlegend drugs within five days of the change [shall be] is ten dollars.

(13) The fee for issuance of a nonresident pharmacy certificate of registration [shall be] is six hundred dollars.

(14) The fee for renewal of a nonresident pharmacy certificate of registration [shall be] is one hundred fifty dollars.

(15) The fee for application for registration as a pharmacy technician [shall be] is fifty dollars.

(16) The fee for renewal of a registration as a pharmacy technician

[shall be] is twenty-five dollars.

(17) The fee for issuance of a temporary permit to practice pharmacy is one hundred dollars.

Sec. 10. Section 20-605 of the general statutes, as amended by section 31 of public act 99-175, is repealed and the following is substituted in lieu thereof:

No individual may engage in the practice of pharmacy unless the individual holds a current license or temporary permit to practice pharmacy issued by the department.

Sec. 11. Section 20-607 of the general statutes, as amended by section 33 of public act 99-175, is repealed and the following is substituted in lieu thereof:

Each person practicing as a pharmacist, pharmacy intern or pharmacy technician shall at all times have available for inspection by an inspector of the department a current certificate of license or temporary permit to practice pharmacy or a current registration to act as a pharmacy intern or pharmacy technician.

Sec. 12. Section 20-608 of the general statutes, as amended by section 34 of public act 99-175, is repealed and the following is substituted in lieu thereof:

A pharmacist who permits such pharmacist's certificate of license, temporary permit or display document to be used by an unlicensed person for unlawful use shall be fined one hundred dollars and shall be subject to other disciplinary proceedings within the authority of the commission.

Sec. 13. Subsection (a) of section 20-613 of the general statutes, as amended by section 35 of public act 99-175, is repealed and the following is substituted in lieu thereof:

(a) Except as provided in subsections (b) and (d) of this section, a drug or a legend device may be dispensed pursuant to a prescription only in a pharmacy or institutional pharmacy by a pharmacist or by a pharmacy intern when acting under the direct supervision of a pharmacist, or by an individual holding a temporary permit.

GL ***Committee Vote:*** Yea 14 Nay 0 JFS

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact: Minimal Revenue Gain, Minimal Revenue Loss

Affected Agencies: Department of Consumer Protection

Municipal Impact: None

Explanation

State Impact:

The bill establishes a temporary permit to practice pharmacy for certain qualified individuals, and establishes a $100 fee. It is anticipated that approximately 75 pharmacists would be eligible and seek a temporary permit per year. Thus, a revenue gain of $7,500 (75 x $100) will result. It is anticipated that the Department of Consumer Protection (DCP) can issue these permits within the current budgetary resources, thus no fiscal impact is anticipated.

Additionally, the bill makes the application for controlled substance registration annual rather than biennial and reduces the fee from $25 for two years to $10 for one year. This may result in a minimal revenue loss because a total of $20 will be collected during the same two year period ($10 the first year for the initial registration application, and $10 the second year for a registration renewal fee as provided under current law) instead of the current $25 for the same period. The extent of the revenue loss is contingent on the number of

individuals or entities applying for a controlled substance registration, and is estimated to be very minimal.

OLR Bill Analysis
sSB 371

AN ACT CONCERNING THE CLASSIFICATION AND REGULATION OF DRUGS BY THE DEPARTMENT OF CONSUMER PROTECTION AND THE ISSUANCE OF A TEMPORARY PERMIT TO PRACTICE PHARMACY.

SUMMARY:
This bill (1) classifies 1,4 butanediol as a "restricted drug or substance," (2) establishes a temporary permit to practice pharmacy for pharmacists licensed in other states, (3) changes requirements for pharmacists to state the expiration date on containers of prescription medicine, (4) alters one of the ways a prescription drug is deemed misbranded, (5) makes controlled substance practitioner registration annual, and (6) makes technical changes.

EFFECTIVE DATE: October 1, 2000

1, 4 BUTANEDIOL

The bill classifies 1,4 butenediol, also known as "BD," as a restricted drug or substance, thereby making it illegal to possess, sell, prescribe, dispense, compound, process, deliver, or administer to another person except as permitted by law. These substances are restricted only if they are used to produce a stimulant, depressant, or hallucinogenic effect by breathing, inhaling, sniffing, or drinking.

TEMPORARY PERMIT

The bill authorizes The Department of Consumer Protection (DCP), when authorized by the Pharmacy Commission, to issue a one-time temporary permit to practice pharmacy to someone who:

1. is licensed in good standing in another state or jurisdiction that grants reciprocal privileges to Connecticut pharmacists,
2. has applied to the Pharmacy Commission for a pharmacy license

based on the fact the pharmacist is licensed in another jurisdiction, and
3. has no actions pending against him in another jurisdiction's pharmacy board or commission.

The bill requires a temporary permit holder to work under the direct supervision of a licensed pharmacist. The permit expires when the pharmacist receives a Connecticut pharmacist license or six months from the date the permit is issued, whichever is sooner. The permit fee is $100.

The bill incorporates the temporary permit into the licensing system for pharmacists. Accordingly, it:

1. allows a temporary permit holder to practice pharmacy and dispense prescription drugs and devices,
2. requires temporary permit holders to have their permit available for inspection, and
3. subjects temporary permit holders to discipline on the same grounds as pharmacists.

EXPIRATION DATES ON PRESCRIPTION DRUGS

The law requires pharmacists to include on each prescription container's label a prominently printed expiration date that can be read and understood by the ordinary individual. The bill requires that the date be based on the manufacturer's recommended conditions of use and storage rather than based on customary conditions of purchase, use, and storage based on the manufacturer's recommended guidelines.

MISBRANDED DRUGS

Under current law, a prescription drug is misbranded if it (1) contains any quantity of certain substances, (2) is one of certain habit-forming drugs, (3) has a toxic or harmful effect or its method of use is unsafe, or (4) is a cosmetic limited to use under the professional supervision of a licensed professional or sold under a prescription. Under the bill, a prescription drug is misbranded if it is not administered, dispensed, prescribed, or otherwise possessed or distributed in accordance with

federal and state law (see BACKGROUND).

CONTROLLED SUBSTANCE PRACTITIONER REGISTRATION

The law requires medical practitioners who distribute, administer, or dispense controlled substances to register with DCP. The bill requires the practitioner to register annually rather than biennially and reduces the renewal fee from $25 to $10.

BACKGROUND

Misbranded Drugs

The law prohibits:

1. obtaining, or attempting to obtain, any misbranded drug or to procure, or attempt to procure, any such drug by (1) fraud, deceit, or subterfuge, (2) forgery, (3) concealment of a material fact, or (4) making a false statement;
2. manufacturing, possessing, controlling, selling, prescribing, administering, dispensing or compounding any such drug except as permitted by law;
3. falsely assuming the title of a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian, or other authorized person to obtain such a drug;
4. forging a prescription to obtain such a drug; or
5. attaching a false label containing such a drug.

The DCP commissioner can investigate and take samples for testing. A violator is subject to a penalty of six months in prison, a fine of up to $500, or both. The penalty is doubled for subsequent convictions and for violations committed with intent to defraud or mislead.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute Report
Yea 14 Nay 0